

CLAIMS

What is claimed is:

1. A kit comprising a therapeutically effective amount of a hydralazine compound or
5 a pharmaceutically acceptable salt thereof, a therapeutically effective amount of isosorbide
dinitrate, and written instructions in a form prescribed by a governmental agency regulating the
manufacture, use or sale of pharmaceuticals, for treating a black patient by administering the
hydralazine compound or the pharmaceutically acceptable salt thereof, and the isosorbide
dinitrate to the black patient.
- 10 2. The kit of claim 1, further comprising a therapeutically effective amount of at
least one compound selected from a digitalis compound, a diuretic compound, and a compound
used to treat a cardiovascular disease.
3. The kit of claim 1, further comprising a therapeutically effective amount of one or
15 more compounds selected from the group consisting of a digitalis compound, a diuretic
compound, potassium, an angiotensin-converting enzyme inhibitor, a beta-adrenergic blocker, a
cholesterol reducer, a calcium channel blocker, an angiotensin II receptor antagonist, and an
endothelin antagonist.
4. The kit of claim 1, wherein the hydralazine compound or the pharmaceutically
acceptable salt thereof and the isosorbide dinitrate are in the form of a composition in the kit.
- 20 5. The kit of claim 1, wherein the hydralazine compound or the pharmaceutically
acceptable salt thereof and the isosorbide dinitrate are separate components in the kit.
6. The kit of claim 1, wherein the hydralazine compound or pharmaceutically
acceptable salt thereof and the isosorbide dinitrate are in a solid dosage form for oral
administration.
- 25 7. The kit of claim 6, wherein the solid dose is in the form of a tablet or a capsule.
8. The kit of claim 7, wherein the capsule is in the form of a sustained release
capsule.
9. The kit of claim 7, wherein the tablet is in the form of a sublingual tablet, a
sustained-release tablet or a chewable tablet.
- 30 10. The kit of claim 1, wherein the hydralazine compound is budralazine, cadralazine,
dihydralazine, endralazine, hydralazine, pildralazine, todralazine or a pharmaceutically

acceptable salt thereof.

11. The kit of claim 10, wherein the hydralazine is hydralazine hydrochloride.

12. The kit of claim 1, wherein the kit comprises the hydralazine compound or the pharmaceutically acceptable salt thereof, for administration in an amount of about 30 milligrams to about 300 milligrams per day and the isosorbide dinitrate for administration in an amount of about 20 milligrams to about 200 milligrams per day.

13. The kit of claim 1, wherein the kit comprises instructions for administering the hydralazine compound or the pharmaceutically acceptable salt thereof, and the isosorbide dinitrate to reduce mortality associated with heart failure in the black patient; to improve oxygen consumption in the black patient; to improve the quality of life for the black patient; and/or to improve exercise tolerance in the black patient.

14. The kit of claim 1, wherein the kit comprises instructions for administering the hydralazine compound or the pharmaceutically acceptable salt thereof, and the isosorbide dinitrate to treat hypertension in the black patient.

15. A kit comprising a therapeutically effective amount of hydralazine hydrochloride, a therapeutically effective amount of isosorbide dinitrate, and written instructions in a form prescribed by a governmental agency regulating the manufacture, use or sale of pharmaceuticals, for treating a black patient by administering the hydralazine hydrochloride and the isosorbide dinitrate to the black patient.

16. The kit of claim 15, wherein the kit comprises the hydralazine hydrochloride for administration in an amount of about 30 milligrams to about 300 milligrams per day and the isosorbide dinitrate for administration in an amount of about 20 milligrams to about 200 milligrams per day.

17. The kit of claim 15, wherein the kit comprises instructions for administering the hydralazine hydrochloride and the isosorbide dinitrate to reduce mortality associated with heart failure in the black patient; to improve oxygen consumption in the black patient; to improve the quality of life for the black patient; and/or to improve exercise tolerance in the black patient.

18. The kit of claim 15, wherein the kit comprises instructions for administering the hydralazine hydrochloride and the isosorbide dinitrate to treat hypertension in the black patient.

19. The kit of claim 15, wherein the hydralazine hydrochloride and the isosorbide dinitrate are in a solid dosage form for oral administration.

20. The kit of claim 19, wherein the solid dose is in the form of a tablet or a capsule.

21. The kit of claim 20, wherein the capsule is in the form of a sustained release capsule.

22. The kit of claim 20, wherein the tablet is in the form of a sublingual tablet, a
5 sustained-release tablet or a chewable tablet.

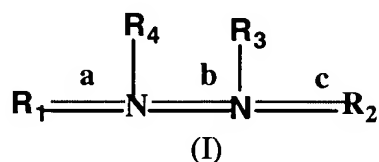
23. The kit of claim 15, further comprising a therapeutically effective amount of at least one compound selected from a digitalis compound, a diuretic compound, and a compound used to treat a cardiovascular disease.

24. The kit of claim 15, further comprising a therapeutically effective amount of one
10 or more compounds selected from the group consisting of a digitalis compound, a diuretic compound, potassium, an angiotensin-converting enzyme inhibitor, a beta-adrenergic blocker, a cholesterol reducer, a calcium channel blocker, an angiotensin II receptor antagonist, and an endothelin antagonist.

25. The kit of claim 15, wherein the hydralazine hydrochloride and the isosorbide
15 dinitrate are in the form of a composition in the kit.

26. The kit of claim 15, wherein hydralazine hydrochloride and the isosorbide dinitrate are separate components in the kit.

27. A kit comprising a therapeutically effective amount of at least one hydralazine
20 compound of Formula (I), or a pharmaceutically acceptable salt thereof, a therapeutically effective amount of at least one of isosorbide dinitrate and isosorbide mononitrate, and written instructions in a form prescribed by a governmental agency regulating the manufacture, use or sale of pharmaceuticals, for treating a black patient by administering at least one hydralazine compound of Formula (I) or the pharmaceutically acceptable salt thereof, and at least one of the isosorbide dinitrate and isosorbide mononitrate to the black patient; wherein the hydralazine
25 compound of Formula (I) is:



wherein a, b and c are each independently a single or a double bond; R₁ and R₂ are each independently a hydrogen, an alkyl, an ester or a heterocyclic ring; R₃ and R₄ are each

independently a lone pair of electrons or a hydrogen, with the proviso that at least one of R₁, R₂, R₃ and R₄ is not a hydrogen.

28. The kit of claim 27, further comprising a therapeutically effective amount of at least one compound selected from a digitalis compound, a diuretic compound, and a compound used to treat a cardiovascular disease.

29. The kit of claim 27, further comprising a therapeutically effective amount of one or more compounds selected from the group consisting of a digitalis compound, a diuretic compound, potassium, an angiotensin-converting enzyme inhibitor, a beta-adrenergic blocker, a cholesterol reducer, a calcium channel blocker, an angiotensin II receptor antagonist, and an endothelin antagonist.

30. The kit of claim 27, wherein the at least one hydralazine compound of Formula (I) or the pharmaceutically acceptable salt thereof, and the at least one of isosorbide dinitrate and isosorbide mononitrate are in the form of a composition in the kit.

31. The kit of claim 27, wherein the hydralazine compound of Formula (I), or the pharmaceutically acceptable salt thereof, and the at least one of isosorbide dinitrate and isosorbide mononitrate are separate components in the kit.

32. The kit of claim 27, wherein the hydralazine compound of Formula (I), or pharmaceutically acceptable salt thereof and the at least one of isosorbide dinitrate and isosorbide mononitrate are in a solid dosage form for oral administration.

33. The kit of claim 32, wherein the solid dose is in the form of a tablet or a capsule.

34. The kit of claim 33, wherein the capsule is in the form of a sustained release capsule.

35. The kit of claim 33, wherein the tablet is in the form of a sublingual tablet, a sustained-release tablet or a chewable tablet.

36. The kit of claim 27, wherein the hydralazine compound of Formula (I) is hydralazine, budralazine, cadralazine, dihydralazine, endralazine, pildralazine or todralazine.

37. The kit of claim 36, wherein the hydralazine compound of Formula (I) is hydralazine hydrochloride.

38. The kit of claim 27, wherein the kit comprises instructions for administering the at least one hydralazine compound of Formula (I) or the pharmaceutically acceptable salt thereof, and at least one of the isosorbide dinitrate and isosorbide mononitrate to reduce mortality

associated with heart failure in the black patient; to improve oxygen consumption in the black patient; to improve the quality of life for the black patient; and/or to improve exercise tolerance in the black patient.

39. The kit of claim 27, wherein the kit comprises instructions for administering the at
5 least one hydralazine compound of Formula (I) or the pharmaceutically acceptable salt thereof, and at least one of the isosorbide dinitrate and isosorbide mononitrate to treat hypertension in the black patient.

40. The kit of claim 27, wherein the kit comprises the hydralazine compound of
Formula (I) or the pharmaceutically acceptable salt thereof, for administration in an amount of
10 about 30 milligrams to about 300 milligrams per day and the isosorbide dinitrate for administration in an amount of about 20 milligrams to about 200 milligrams per day or the isosorbide mononitrate for administration in an amount of about 10 milligrams to about 120 milligrams per day.

15